

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT



(PCT Article 36 and Rule 70)

Applicant's or agent's file reference INO10504PCT	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/EP 03/06856	International filing date ( <i>day/month/year</i> ) 27.06.2003	Priority date ( <i>day/month/year</i> ) 04.07.2002
International Patent Classification (IPC) or both national classification and IPC A61M16/10		
Applicant INO THERAPEUTICS GMBH et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 5 sheets, including this cover sheet.
  - ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of    sheets.

3. This report contains indications relating to the following items:
  - I    ☒ Basis of the opinion
  - II   ☐ Priority
  - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
  - IV   ☐ Lack of unity of invention
  - V    ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
  - VI   ☐ Certain documents cited
  - VII ☐ Certain defects in the international application
  - VIII ☐ Certain observations on the international application

Date of submission of the demand  19.01.2004	Date of completion of this report  19.07.2004
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Borowski, A  Telephone No. +49 89 2399-2758 

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP 03/06856

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-10 as originally filed

**Claims, Numbers**

1-21 as originally filed

**Drawings, Sheets**

1/2-2/2 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:
- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
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International application No. **PCT/EP 03/06856**

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 1-13, 21

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 1-13, 21

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	17-20
	No: Claims	14-16
Inventive step (IS)	Yes: Claims	17
	No: Claims	14-16, 18-20
Industrial applicability (IA)	Yes: Claims	14-20
	No: Claims	

2. Citations and explanations

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claims 1-13 and 21 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT: *a method for administering carbon monoxide to a patient*. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: GB-A-1 581 482 (DRAEGERWERK AG) 17 December 1980 (1980-12-17)
- D2: WO 01 41856 A (PULMONOX MEDICAL CORP ;MILLER CHRIS C (CA); MILLER JOHN W R (CA);) 14 June 2001 (2001-06-14)
- D3: EP-A-0 524 083 (EFFETS BIOLOGIQUES EXERCICE) 20 January 1993 (1993- 01-20) cited in the application

- V.1 Independent claim 14 does not contain any features which meet the requirements of the PCT (Article 33(3) PCT) in respect of novelty, as all features of said claim all already known from document D1 (see page 1, lines 83-87, page 3, lines 13-113 and figure).

All features of dependent claims 15 and 16 are also known from document D1 (see passages cited in the search report).

- V.2 Dependent claims 18-20 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step (Article 33(3) PCT), the reasons being as follows:

Document D1, which discloses an apparatus for administering carbon monoxide to a patient is considered to represent the most relevant state of the art. The subject-

matter of claims 18-20 differs from said apparatus in that:

- the sensor is connected to an alarm unit (claim 18);
- the sensor measures concentration of carboxyhemoglobin (claim 19);
- the apparatus comprises a filter unit for removing an excess of CO from exhaled air (claim 20).

The problems to be solved by differentiating features may therefore be regarded as:

- how to protect a patient from an overdosis of CO (claim 18);
- how to enable an effective administration of CO to a patient (claim 19);
- how to protect the environment from the CO pollution (claim 20).

The features of claims 18 and 19 have already been employed for same purposes in similar devices, see documents D2 (page 18, lines 21-29) for claim 18 and D3 (entire) for claim 19. It would therefore be obvious to the person skilled in the art, to apply these features with corresponding effect to a device according to document D1, thereby arriving at an apparatus according to claims 18 and 19.

The feature of claim 20 is merely one of several straightforward possibilities from which the skilled person would select, in accordance with circumstances, without the exercise of inventive skill, in order to solve the problem posed.

- V.3 The combination of the features of dependent claim 17 (apparatus comprising at least two independently working sensor means for a determination of carbon monoxide in the blood) is neither known from, nor rendered obvious by, the available prior art. An application of plural CO sensors improves the safety in a process for administering carbon monoxide to a patient.
- V.4 Independent claim 14 should have been written in the two-part form in accordance with Rule 6.3(b) PCT.
- V.5 The features of the claims should have been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).